

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/313, 628 05/18/99 HODGEN

G P/1890-201 (D)

HM12/0224

OSTROLENK, FABER, GERB & SOFFEN LLP
1180 AVENUE OF THE AMERICAS
NEW YORK NY 10036-8403

EXAMINER

MOEZIE, M

ART UNIT	PAPER NUMBER
----------	--------------

1617

6

DATE MAILED:

02/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/313,628	Applicant(s) Hodgen
	Examiner M. MOEZIE	Group Art Unit 1617

Responsive to communication(s) filed on Nov 12, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-20 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1617

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "SERM" in claims 1-3,7 and 14-15 is used by the claim to mean "non-agonist selective modulators of the estrogen receptor," while the accepted meaning is "a compound modulating estrogen receptor activity in any fashion."

Claims 1-13 are indefinite as to how the control and regulation of estrogenic impact on "specific tissues and organs" would be useful in a method of contraception. See claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371C of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Garfield et al.

This rejection is of record in the prior office action.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5, and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Garfield et al.

The claims are rejected over Garfield et al. essentially for reasons of record in the prior office action. The rejection of claim 14 is being made under 35 U.S.C. 103 in this office action since Garfield is not seen to expressly teach the kit aspect of applicant's invention.

Applicant's remarks in Paper No.5, submitted November 12, 1999, regarding the induction of ovulation by clomiphene are persuasive as to the non-obviousness of the employment of this particular SERM in the claimed contraceptive methods and kits herein over Garfield et al.

Applicant's further remarks regarding the scope of the term SERM in light of the disclosure in Garfield et al have been considered but are not persuasive since the claims employ the term, SERM, which clearly encompasses selective modulators for the estrogen receptor which are agonists, e.g., estrogen, as well as modulators which have antagonistic activity at the estrogen receptor, e.g., antiestrogens.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., Poulin et al., Black et al., and DiPiro et al.

Art Unit: 1617

The claims are rejected over Tanaka et al., Poulin et al. and DiPiro et al. for reasons of record in the prior office action.

Black et al. (Provided by applicant in the IDS of May 18, 1999) has been added to the instant rejection since it provides further motivation for the instant kit. Black et al. teach that SERM antiestrogenic compounds encompassed by the claims are known to be useful in compositions for the treatment of osteoporosis in combination with progestogenic actives within the instant claims. See especially col.2, lines 43-58 regarding antiestrogenic and progestogenic-antiestrogenic compounds, col.3, lines 47-53, and column 6, especially at lines 46-60 for effective amounts of antiestrogenic and progestogenic compounds.

The employment of a composition containing compounds known or expected to be useful together for a particular purpose, in a kit useful for the same purpose, is considered clearly obvious.

Applicant's remarks in Paper No.5 regarding the contraceptive purpose or use for the claimed kit have been considered but are not persuasive. It is not seen that the effective amounts of agents herein for contraception differ from the prior art. See, e.g., applicants examples at page 11 in the specification and Black et al., col.6, lines 46-60.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Moezie whose telephone number is (703) 308-4612. The examiner can normally be reached on Monday to Friday from 8:30am to 6:00pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Moezie/sg

February 16, 2000


MINNA MOEZIE
PRIMARY EXAMINER